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# Test and Evaluation Report of the Physio Control Defibrillator/Monitor Model LIFEPAK® 8

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The Physio Control Defibrillator/Monitor Model LIFEPAK® 8 was tested for electromagnetic interference/compatibility in the UH-60A helicopter under the U.S. Army Program for Testing and Evaluation of Equipment for Aeromedical Operations. The tests were conducted using current military and industrial standards and procedures for electromagnetic interference/compatibility and human factors. The LIFEPAK® 8 was found to be compatible with U.S. Army modical evacuation UH-60A Blackhawk.						
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#### Section 1. Executive digest

The Army program for Test and Evaluation of Aeromedical Equipment uses existing military standards (MIL-STD) and collective professional expertise to test and evaluate selected medical equipment proposed for use aboard Army aircraft. Equipment meeting these standards ensures the safety of the crew, patients, and aircraft by eliminating risks due to: (1) Interference by the medical equipment with aircraft systems/subsystems operation, (2) by the aircraft system's interference with the operation of the medical equipment, (3) the medical equipment's susceptibility to environmental exposure, or (4) physical and/or functional incompatibility while in use on board selected rotary-wing aircraft. This program tests both developmental and nondevelopmental (off the shelf) medical equipment destined for use aboard Army medical evacuation aircraft.

#### 1.1 TEST OBJECTIVES

- 1.1.1 To determine if the medical equipment is complete and operational per the manufacturer's operating instructions.
- 1.1.2 To ensure the electrical safety of the medical equipment.
- 1.1.3 To ensure the equipment will function as designed throughout the rated battery operation time.
- 1.1.4 To ensure the safety of the operator, the patient, and the aircrew.
- 1.1.5 To assess design considerations which potentially could contribute to an operator error.
- 1.1.6 To determine if the medical equipment can function as designed in a low pressure environment.
- 1.1.7 To determine the ability of the medical equipment to withstand the vibrational stresses expected in a rotary-wing flight environment without degradation or malfunction.
- 1.1.8 To determine the ability of the medical equipment to be stored and operated in a high temperature environment.
- 1.1.9 To determine the ability of the medical equipment to be stored and operated in a low temperature environment.
- 1.1.10 To determine the ability of the medical equipment to operate satisfactorily for short periods of time during exposure to highly humid conditions.
- 1.1.11 To assess the levels of electromagnetic emissions produced by the medical equipment within selected frequency ranges.

- 1.1.12 To assess the minimum electromagnetic susceptibility levels of the medical equipment within selected frequency ranges.
- 1.1.13 To assess the physical and/or functional compatibility of the medical equipment while in use on board the aircraft.
- 1.1.14 To assess the electromagnetic interference (EMI) and electromagnetic compatibility (EMC) characteristics of the medical equipment with the host aircraft and its installed systems.

#### 1.2 TESTING AUTHORITY

Research and Technology Work Unit Summary, dated 5 October 1989. Project number 3M463807D836, titled, Army Program for Testing and Evaluation of Equipment for Aeromedical Operations.

#### 1.3 SCOPE

- 1.3.1 This test was conducted at the United States Army Aeromedical Research Laboratory (USAARL), Cairns Army Airfield (CAAF), and designated test flight areas in and around Fort Rucker, Alabama.
- 1.3.2 The USAARL UH-60A aircraft, serial number 88-26069, with subsystems delineated in paragraph 3.2.2, was configured with the Physio Control defibrillator/monitor, model LIFEPAK® 8 and used as the test aircraft for the in-flight evaluation. The in-flight evaluation required 3.8 flight hours.
- 1.3.3 Laboratory testing was accomplished at USAARL using government furnished equipment (GFE) by Universal Energy Systems, Inc. (UES), under contract No. DAMD 17-86-C-6215.
- 1.3.4 Prior to flight testing the following tests were accomplished: Acceptance inspection, equipment training, electromagnetic compatibility, human factors and safety, environmental compatibility, and in-flight compatibility.
- 1.3.5 An air worthiness release (AWR) dated 16 Aug 1990 was received from the U.S. Army Aviation Systems Command (AVSCOM) prior to the in-flight testing of the LIFEPAK\* 8.

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#### 1.4 MATERIAL DESCRIPTION

The Physio Control LIFEPAK® 8 defibrillator/monitor\* is a modular system in which the units may be used together or separately. The electrocardiograph (ECG) monitor has a cathode ray tube (CRT) cardioscope which displays real time ECG and digital indications of heart rate, alarm settings, and trace size. A paper strip chart recorder is also included. The defibrillator module has eight selectable energy levels which are discharged via two paddles stored upright on the front panel.

#### 1.5 SUMMARY

#### 1.5.1 Laboratory testing

- 1.5.1.1 Battery Life Evaluation: The battery in the LIFEPAK® 8 defibrillator provided power for an average of 21 full power energize-fire cycles and 2 hours standby time. The monitor battery provided power for an average of 2.5 hours continuous monitoring time. These times are consistent with the operator manual specifications of 25 consecutive defibrillator cycles and 2.5 hours monitoring time.
- 1.5.1.2 Electrical Safety Evaluation: All measurements were within acceptable limits. No unsafe qualities were found in the LIFEPAK® 8. The limits for currents and resistances were in accordance with (IAW) the National Fire Prevention Association (NAFP) standards.
- 1.5.1.3 Human Factors Evaluation: The LIFEPAK® 8 defibrillator may be difficult to operate because there is limited clearance around the paddle handles. When the external pacer cassette is installed, it obstructs the carrying handle on the defibrillator. The LIFEPAK® 8 system may be too heavy to be considered portable. There is no provision to vary the indicator intensity. All other evaluation criteria were met satisfactorily. Standards referenced include MIL-STD-1472D, AAMI Human Factors Engineering Guidelines, and UL-544.
- 1.5.1.4 Environmental Tests: The LIFEPAK® 8 can be expected to perform in a variety of environmental conditions. Its performance was found to be satisfactory in all stages of the environmental testing, except humidity. The synchronized defibrillation mode was not functional during exposure to the test humidity, but became operational after the system was returned to ambient conditions. The requirements for environmental tests are established in MIL-STD-810D, methods 500.2 (altitude), 514.3 (vibration), 501.2 (high temperature), 502.2 (low temperature) and 507.2 (humidity).

<sup>\*</sup> See manufacturer's list

- 1.5.1.5 Radiated Emissions Tests (REO2): The LIFEPAK® 8 may be unsatisfactory for use in certain EMI sensitive environments. Narrowband and broadband emissions were detected in the test frequency ranges. Some narrowband and broadband emissions exceeded the test limits. Emission limits are set forth in MIL-STD-461A, Notice 4.
- 1.5.1.6 Radiated Susceptibility Test (RS03): Susceptibility to the radiated test interference was noted in the LIFEPAK $^{\oplus}$  8 at frequencies of 20 to 20.8 MHz, 30 MHz, and 30 to 40.2 MHz. Erratic displays, erratic recordings, and service alert displays occurred as a result of this interference.
- 1.5.1.7 Conducted Emissions Test (CE01, CE02, and CE04): Conducted emissions were measured in the frequency range 34 kHz to 50 MHz at levels 0.1 to 38.7 dB over specification limits, NB, and in the frequency range 1 to 15 MHz at levels 0.5 to 30.6 dB over specification limits, BB.
- 1.5.1.8 Conducted Susceptibility Test (CS02 and CS06): No susceptibility to the test power line spikes was noted in the LIFEPAK® 8 defibrillator/monitor.

#### 1.5.2 In-flight testing

- 1.5.2.1 During the in-flight human factors evaluation, the LIFEPAK® 8 was found to be satisfactory in all but two categories of the evaluation criteria. First, the human factors deficiencies noted in the laboratory evaluation (paragraph 1.5.1.3) were exacerbated by the cramped quarters in the aircraft. Second, the flight surgeon was unable to hear any audio alarms while wearing the required flight ensemble with background aircraft noise.
- 1.5.2.2 The aircraft and its subsystems were not adversely affected by the operation of the LIFEPAK® 8 in any of the prescribed flight test profiles.
- 1.5.2.3 The LIFEPAK $^{\bullet}$  8 was not affected by the aircraft and its subsystems during the in-flight testing.

#### 1.6 CONCLUSIONS

Based on the results of laboratory and in-flight testing, the LIFEPAK\* 8 was found to be compatible with the U.S. Army medical evacuation UH-50A Blackhawk with the subsystems listed in paragraph 3.2.2.

#### Section 2. Subtests

#### 2.1 INITIAL INSPECTION

#### 2.1.1 Objective

To determine if the LIFEPAK\* 8 is complete and operational for testing per the manufacturer's operating instructions.

#### 2.1.2 Criteria

- 2.1.2.1 The physical inventory is conducted solely for investigation and documentation.
- 2.1.2.2 The LIFEPAK® 8 will display a consistent and accurate measurement of simulated ECG signals within ± 2 percent and deliver the programmed defibrillator energy within 3 percent.

#### 2.1.3 Test procedure

- 2.1.3.1 A complete physical inventory of the LIFEPAK $^{\oplus}$  8 was completed per the manufacturer's equipment list.
- 2.1.3.2 An operational validation test of the LIFEPAK® 8 was conducted per the manufacturer's operating instructions by USAARL's medical maintenance personnel.

#### 2.1.4 Test findings

- 2.1.4.1 The LIFEPAK® 8 was inventoried and found to be complete.
- 2.1.4.2 The LIFEPAK® 8 operated as prescribed in the manufacturer's operating manual, P/N 803334-02. Criterion met.
- 2.2 BATTERY LIFE EVALUATION (Laboratory)

#### 2.2.1 Objective

To ensure the equipment will function as designed throughout the rated battery operation time.

#### 2.2.2 Criteria

- 2.2.2.1 Verify manufacturer's specified full power battery life expectancy of 2.5 hours during continuous cardioscope monitoring of a simulated ECG rate of 60 beats per minute (BPM).
- 2.2.2.2 Verify manufacturer's specified full power battery life expectancy of 25 360-joule discharges.
- 2.2.2.3 Ensure battery is capable of supplying a minimum of 1.5 hours continuous use to support MEDEVAC mission.

#### 2.2.3 Test procedure

- 2.2.3.1 Charging and operation cycles were conducted in ambient room conditions of 23°C, 40-60 percent relative humidity (RH).
- 2.2.3.2 The LIFEPAK® 8 was operated continuously for an average of 2 hours from a fully charged battery. At 1-hour intervals the defibrillator was energized to 360 joules and fired 10 consecutive times.

#### 2.2.4 Test findings

The monitor operated continuously for an average of 2.5 hours before a low battery indication was displayed. An average of 21 energize-fire cycles were completed before a low battery indication was displayed. This performance is consistent with the manufacturer specification of 2.5 hours monitor operation and 25 defibrillator energize-fire cycles. Criterion met.

#### 2.3 ELECTRICAL SAFETY EVALUATION

#### 2.3.1 Objective

To ensure the electrical safety, by evaluation of case-to-ground resistance and case-to-ground current leakage, of the LIFEPAK $^{ullet}$  8.

#### 2.3.2 Criterion

The LIFEPAK® 8 shall meet the standards established in NFPA 99 for electrical safety of medical equipment.

#### 2.3.3 Test procedure

Measurements in the electrical safety evaluation were made with a Neurodyne-Dempsey model 431F electrical safety analyzer\*, IAW the procedures described in Technical Bulletin (TB) Number 38-750-2. Case-to-ground resistance and various case-to-ground leakage currents were measured. Leakage currents were measured using a 10 by 20 centimeter aluminum foil sheet taped flush to the equipment case. Checks were made for safety concerns, such as case integrity, breaks in power cord insulation, and connectors.

#### 2.3.4 Test findings

Grounding conductor resistance was 57.7 milliohms and maximum case leakage current was 53 microamperes. Maximum ECG lead leakage current was 2.5 microamperes. Maximum leakage current from the defibrillator paddles was 8.2 microamperes. Delivered energy was within 3 percent of the selected energy at

- all levels. Maximum charge time was 10 seconds with AC power and a fully charged battery. These measurements are below the criteria specified in NFPA 99. Criterion met.
- 2.4 HUMAN FACTORS EVALUATION (Laboratory)

#### 2.4.1 Objectives

- 2.4.1.1 To assure the safety of the operator, the potential patient, and the aircrew.
- 2.4.1.2 To assess the design considerations which could potentially contribute to an operator error.

#### 2.4.2 Criterion

The LIFEPAK\* 8 must be rated satisfactory in all major categories of the evaluation. These include visual displays, controls, maintainability, conductors, fasteners, test points, test equipment, fuses and circuit breakers, labels and coding, and safety.

#### 2.4.3 Test procedure

- 2.4.3.1 The evaluation was conducted in a laboratory under fluorescent lighting and ambient room conditions.
- 2.4.3.2 The LIFEPAK\* 8 was operated according to prescribed instructions through its full range of functions.

#### 2.4.4 Test finding

The LIFEPAK® 8 was found to be unsatisfactory in two of the evaluation criteria: Controls and maintainability. The defibrillator paddle handles are located in "wells" which make them difficult to grasp and hold to the patient, especially with gloved hands. There is no control to vary the display intensity which may be required for night operations. When the external pacer cassette is installed, it obstructs the carrying handle on the defibrillator. The unit weight of 36.2 lbs (16.46 kg) may be too cumbersome or heavy for use as a portable device. Criterion partially met.

2.5 ALTITUDE (LOW PRESSURE) TEST (IAW METHOD 500.2, MIL-STD-810D)

#### 2.5.1 Objective

To determine it the LIFEPAK\* 8 can function as designed in a low pressure environment.

#### 2.5.2 Criterion

The LIFEPAK® 8 will display consistent and accurate measurement of simulated ECG signals within ± 1 beat and deliver the programmed defibrillator energy within 1 joule while exposed to an altitude equivalency of 15,000 flet above sea level.

#### 2.5.3 Test procedure

- 2.5.3.1 A pretest performance check was conducted to ensure proper operation of the LIFEPAK® 8.
- 2.5.3.2 The Altitude Test was performed in a Tenney Engineering model 64S altitude chamber\*. This test is based on MIL-STD-810D, Method 500.2. The LIFEPAK\* 8 was placed in operation near the center of the floor of the chamber. The LIFEPAK\* 8 was turned on by means of a remote arm through the chamber wall and monitored a signal from an ECG simulator during the test. The defibrillator was not discharged during this test because there are no provisions for operation from outside the chamber. Chamber pressure was decreased to 420 mmHg (15,000 ft equivalent altitude) over a 15-minute period, held constant for 60 minutes, then raised, at 1500 fpm, to ambient conditions (760 mmHg) over a 10-minute period. There are no provisions for the control of temperature or humidity inside this chamber.
- 2.5.3.3 A posttest performance check was conducted to ensure proper operation of the LIFEPAK $^{\oplus}$  8 after the exposure to low pressure.

#### 2.5.4 Test findings

- 2.5.4.1 The pretest performance check met criterion 2.1.2.2.
- 2.5.4.2 No failures in the LIFEPAK® 8's performance were noted before, during, or after the altitude test. Criterion met.
- 2.5.4.3 The posttest performance check met criterion 2.1.2.2.
- 2.6 VIBRATION TEST [IAW METHOD 514.3, MIL-STD-810D]

#### 2.6.1 Objective

To determine the ability of the LIFEPAK® 8 to withstand the vibrational stresses expected in a rotary-wing environment without degradation or malfunction.

#### 2.6.2 Criterion

While exposed to vibrational stresses, the LIFEPAK® 8 will remain operational and be able to display consistent and accurate

measurement of simulated ECG signals within  $\pm$  1 beat and deliver the programmed defibrillator energy within 1 joule.

#### 2.6.3 Test procedure

- 2.6.3.1 A pretest performance check was conducted to ensure proper operation of the LIFEPAK\* 8.
- 2.6.3.2 The vibration test was performed using an Unholtz-Dickey model TA115-40/CSTA vibration test system\*. It is a single-axis system with an electromagnetic driver unit. The test consisted of sinusoidal vibrations, superimposed on random vibrations over a frequency range of 500 Hz, as shown below. These vibrations are derived from measurements taken on the floor under the copilot's seat in a UH-1 helicopter traveling at 120 knots. The reference spectrum breakpoints are from MIL-STD-810D, Method 514.3; reference spectrum levels are based on field measurements with a conservatism factor of 1.5. Independent tests were conducted in the X, Y, and Z axes.

#### Z-axis

duration: 60 minutes broadband intensity: 0.4506  $G_{mn}$  random vibration: initial slope : 99.00 dB/Hz 5 Hz level: 0.00006210  $G_{npr Hz}$  100 Hz level: 0.0006210  $G_{npr Hz}$  300 Hz level: 0.0006210  $G_{npr Hz}$  500 Hz level: 0.00006210  $G_{npr Hz}$  500 Hz level: 0.00006210  $G_{npr Hz}$  final slope: -99.00 dB/oct sinusoidal vibration: .5450  $G_{pk}$  at 11.25 Hz .1690  $G_{pk}$  at 22.50 Hz .1200  $G_{pk}$  at 33.75 Hz .0310  $G_{pk}$  at 45.00 Hz .0530  $G_{pk}$  at 56.25 Hz

#### X and Y axes

duration: 60 minutes each broadband intensity: 0.3099 G<sub>mm</sub>; random vibration: initial slope: 99.00 dB/oct 5 Hz level: 0.00002920 G<sub>mm</sub>; Hz level: 0.0002920 G<sub>mm</sub>; Hz level: 0.0002920 G<sub>mm</sub>; Hz level: 0.0002920 G<sub>mm</sub>; Hz level: 0.00002920 G<sub>mm</sub>; Hz level: 0.00002920 G<sub>mm</sub>; Hz final slope: -99.00 dB/oct sinusoidal vibration: .3200 G<sub>mm</sub>; at 11.25 Hz .0670 G<sub>mm</sub>; at 22.50 Hz .0950 G<sub>mm</sub>; at 33.75 Hz .0350 G<sub>mm</sub>; at 45.00 Hz .0770 G<sub>mm</sub>; at 56.25 Hz

The LIFEPAK® 8 was strapped to the vibration table fixture, and its performance was evaluated before, during, and after exposure to vibration. ECG signals were provided by a Valmedix simulator\*. Defibrillator discharge energy was measured with a Dynatech Nevada defibrillator analyzer\*.

2.6.3.3 A posttest performance check was conducted to ensure proper operation of the LIFEPAK® 8.

#### 2.6.4 Test findings

- 2.6.4.1 The pretest performance check met criterion 2.1.2.2.
- 2.6.4.2 No failures in the LIFEPAK® 8's performance occurred before, during, or after exposure to vibration. Maximum artifact of 1 mm was observed on ECG display and strip chart recordings during vibration exposure in the Z axis. These vibration artifacts may obscure fine details (P, Q, and S waves) in a low amplitude ECG signal. However, heart rate and R wave detection was not compromised. Criterion met.
- 2.6.4.3 The posttest performance check met criterion 2.1.2.2.
- 2.7 HIGH TEMPERATURE TEST [IAW METHOD 501.2, MIL-STD-810D]

#### 2.7.1 Objective

To determine the ability of the LIFEPAK® 8 to be stored and operated in a high temperature environment.

#### 2.7.2 Criteria

- 2.7.2.1 During the high temperature operation check, the LIFEPAK® 8 must display consistent and accurate measurement of simulated ECG signals within ± 2 percent and deliver the programmed defibrillator energy within 3 percent.
- 2.7.2.2 After the high temperature storage cycle, the LIFEPAK\* 8 must be able to display consistent and accurate measurement of simulated ECG signals within ± 2 percent and deliver the programmed defibrillator energy within 3 percent.

#### 2.7.3 Test procedure

- 2.7.3.1 A pretest performance check was conducted to ensure proper operation of the LIFEPAK\* 3.
- 2.7.3.2 The high temperature test was conducted in a Tenney Engineering model ZWUL-10107D Walk-in Controlled Environment Chamber\*. This test is based on MIL-STD-810D, Method 501.2. For the high temperature operation test, the LIFETSK® 8 was placed in operation on a wire test stand near the center of the

environmental chamber. The ECC leads were routed through a portal in the chamber wall to a Valmedix ECG simulator. Defibrillator energy was measured with a Dynatech Nevada defibrillator analyzer. The chamber temperature was raised to 49°C and the humidity was stabilized at a maximum of 20 percent RH within 15 minutes. The environmental control system is capable of regulating temperature within ± 2°C and humidity within ± 5 percent RH. Temperature and humidity were held constant for 2 hours. At 30-minute intervals, the chamber door was opened briefly to minimize the change in chamber conditions during performance checks. After the operational test, the LIFEPAK® 8 was allowed to return to ambient conditions over a 30-minute period.

- 2.7.3.3 A posttest performance check was conducted to ensure proper operation of the LIFEPAK® 8.
- 2.7.3.4 The LIFEPAK® 8 was stored (not operated) at temperatures of 63°C for 1 hour, 71°C for 4 hours, then again at 63°C for 1 hour. The ECG cable was coiled and placed on top of the defibrillator/monitor and the paddles were stored in their holders. The chamber and LIFEPAK® 8 then were returned to ambient conditions over a 30-minute period.
- 2.7.3.5 A poststorage performance check was conducted to ensure proper performance of the LIFEPAK\* 8.

#### 2.7.4 Test findings

- 2.7.4.1 The pretest performance check met criterion 2.1.2.2.
- 2.7.4.2 No operational failures occurred during the high temperature test. Criterion met.
- 2.7.4.3 The posttest performance check met criterion 2.1.2.2.
- 2.7.4.4 The LIFEPAK® 8 functioned properly after the high temperature storage test. Criterion met.
- 2.8 LOW TEMPERATURE TEST [IAW METHOD 502.2, MIL-STD-810D]

#### 2.8.1 Objective

To determine the ability of the LIFEPAK\* 8 to be stored and operated in a low temperature environment.

# 2.8.2 Criteria

2.8.2.1 During the low temperature operation check, the LIFEPAK\* 8 must display consistent and accurate measurement of simulated ECG signals within  $\pm$  2 percent and deliver the programmed defibrillator energy within 3 percent.

2.8.2.2 After the low temperature storage cycle, the LIFEPAK® 8 must be able to display consistent and accurate measurement of simulated ECG signals within ± 2 percent and deliver the programmed defibrillator energy within 3 percent.

#### 2.8.3 Test procedure

- 2.8.3.1 A pretest performance check was conducted to ensure proper operation of the LIFEPAK® 8.
- 2.8.3.2 The LIFEPAK® 8 was placed on the floor of the environmental chamber and the temperature was lowered to 0°C within 25 minutes. The environmental control system is capable of regulating temperature within 2°C. Humidity cannot be controlled in the chamber at freezing temperatures. The temperature was held constant for 2 hours. The chamber door was opened briefly, to minimize the change in chamber conditions, every 30 minutes and a performance check was conducted. The chamber temperature then was raised to ambient temperature within a 30-minute period.
- 2.8.3.3 A posttest performance check was conducted to ensure proper operation of the LIFEPAK® 8.
- 2.8.3.4 The LIFEPAK® 8 was "stored" in a nonoperational mode with the power cord coiled and placed on top of the LIFEPAK® 8. The LIFEPAK® 8 was placed on the floor of the environmental test chamber and the temperature was lowered to -46°C for 6 hours. The chamber was then raised to ambient temperature over a 30-minute period.
- 2.8.3.5 A poststorage performance check was conducted to ensure proper operation of the LIFEPAK® 8.

#### 2.8.4 Test findings

- 2.8.4.1 The pretest performance check met criterion 2.1.2.2.
- 2.8.4.2 No operational failures occurred during the low temperature test. Criterion met.
- 2.8.4.3 The posttest performance check met criterion 2.1.2.2.
- 2.8.4.4 The LIFEPAK® 8 functioned properly after the low temperature storage test. Criterion met.

2.9 HUMIDITY TEST [IAW METHOD 507.2, MIL-STD-810D]

#### 2.9.1 Objective

To determine the ability of the LIFEPAK® 8 to operate satisfactorily for short periods of time during exposure to highly humid conditions.

#### 2.9.2 Criterion

While exposed to a high humidity environment, the LIFEPAK $^{\oplus}$  8 must display consistent and accurate measurement of simulated ECG signals within  $\pm$  2 percent and deliver the programmed defibrillator energy within 3 percent.

#### 2.9.3 Test procedure

- 2.9.3.1 A pretest performance check was conducted to ensure the proper operation of the LIFEPAK® 8.
- 2.9.3.2 The humidity test was conducted in a Tenney Engineering model ZWUL-10107D Walk-in Controlled Environment Chamber\*. This test is based on MIL-STD-810D, Method 507.2. For the humidity test, the LIFEPAK® 8 was placed in operation on a wire test stand near the center of the environmental chamber. The ECG leads were routed through a portal in the chamber wall to a Valmedix ECG simulator\*. Defibrillator energy levels were measured with a Dynatech Nevada defibrillator analyzer\*. The chamber temperature was raised to a temperature of 29.5°C and a relative humidity of 95 percent within 25 minutes. Temperature and relative humidity were maintained for 4 hours. The environmental control system is capable of regulating temperature within ± 2°C and humidity within ± 5 percent RH. At 45-minute intervals the defibrillator/monitor performance was checked. The chamber door was opened briefly to minimize the change in chamber conditions. chamber and the LIFEPAK® 8 were returned to ambient conditions before the posttest performance validation check was conducted.
- 2.9.3.3 A posttest performance check was conducted to ensure the proper operation of the LIFEPAK\* 8.

#### 2.9.4 Test findings

- 2.9.4.1 The pretest performance check met criterion 2.1.2.2.
- 2.9.4.2 A failure was noted in the LIFEPAK\* 8 synchronized defibrillation mode during performance checks conducted during the exposure to the high humidity environment. The synchronized defibrillation mode became nonfunctional during exposure to high numidity, but became operational upon return to ambient conditions. Nonsynchronized defibrillation was still possible. Criterion partially met.

- 2.9.4.3 The posttest performance check met criterion 2.1.2.2.
- 2.10 ELECTROMAGNETIC CHARACTERISTICS TEST [IAW MIL-STD-461A, Notice 4, and MIL-STD-462, Notice 3]

#### 2.10.1 Objectives

- 2.10.1.1 To assess the maximum levels of radiated electromagnetic emissions produced by the LIFEPAK $^{\oplus}$  8 in the 14 kHz to 1.0 GHz frequency range.
- 2.10.1.2 To assess the tolerances of radiated electromagnetic susceptibility of the LIFEPAK® 8 within the 10 kHz to 10 GHz broadband electric field and the 14 kHz to 12.4 GHz narrowband.
- 2.10.1.3 To assess the maximum levels of conducted electromagnetic emissions produced by the LIFEPAK $^{\bullet}$  8 in the 10 kHz to 50 MHz frequency ranges.
- 2.10.1.4 To assess the tolerances of conducted electromagnetic susceptibility of the LIFEPAK\* 8 within the range of 50 kHz to 400 MHz and power spikes.

#### 2.10.2 Criteria

- 2.10.2.1 The LIFEPAK® 8 shall not produce emissions in excess of the limits set forth in paragraph 6.13, MIL-STD-461A, Notice 4.
- 2.10.2.2 The LIFEPAK® 8 shall not malfunction when it is subjected to radiated emissions as specified in paragraph 6.20, MIL-STD-461A. Notice 4.
- 2.10.2.3 The LIFEPAK® 8 shall not conduct emissions in excess of the limits set forth in MIL-STD-461A, Notice 4, paragraphs 6.1 and 6.2.
- 2.10.2.4 The LIFEPAK® 8 shall not malfunction when it is subjected to conducted emissions as specified in MIL-STD-461A, Notice 4, paragraphs 6.7 and 6.10.

#### 2.10.3 Test procedure

2.10.3.1 The radiated emissions test was performed according to MIL-STD-462, Notice 3, Method REO2. The LIFEPAK® 8 was positioned on a wooden test stand 1 meter tall, 0.18 meters wide, and 0.21 meters long, inside the electromagnetic interference (EMI) chamber. The unit was directly in line with, and at a horizontal distance of 1 meter from the receiving antennas. The antennas were mounted for both vertical and horizontal polarities and connected to the appropriate EMI receivers. Electrometrics EMC-25 and EMC-50 receivers were used for this test. Their frequency ranges in testing are 14 kHz to 1 GHz and 1 to 12.4 GHz.

Broadband and narrowband detection methods were used from 14 kHz to 1 GHz. Narrowband detection methods were used from 1 to 12.4 GHz. The monitor operated continuously while displaying ECG signals provided by a Valmedix ECG simulator\*. The defibrillator was charged to 100 joules and discharged into a Dynatech Nevada defibrillator\* analyzer at 20-second intervals.

- 2.10.3.2 The radiated susceptibility test was performed according to MIL-STD-462, Notice 3, Method RSO3. The LIFEPAK® 8 was positioned on a wooden test stand 1 meter tall, 0.18 meters wide, and 0.21 meters long, inside the EMI chamber. The unit was directly in line with, and at a horizontal distance of 1 meter from, the transmitting antennas. The antennas were mounted for both vertical and horizontal polarities and connected to radio frequency (RF) transmitters. The defibrillator/monitor was exposed to fields of 10 V/m from 200 MHz to 2 GHz, and 5 V/m from 2 to 10 GHz. All RF carrier waves were 50 percent amplitude modulated with a 1000 Hz tone. The ECG leads were routed through a wave guide tube through the chamber wall. ECG signals were provided by a Valmedix ECG simulator. The defibrillator was in standby mode during this test.
- 2.10.3.3 The conducted emissions tests were performed according to MIL-STD-462, Notice 3, Methods CE02 and CE04. The LIFEPAK® 8 was placed on a grounded, copper covered workbench. The top of the workbench was 1 meter from floor level, 1.37 meters long, and 0.81 meters wide. Power was supplied via a pair of line impedance stabilization networks (LISN's) and a test jig. The test jig is a wooden tray with two power receptacles and two slots to hold current probes in place around power supply conductors. While the LIFEPAK® 8 was operating, the frequency range (10 kHz to 50 MHz) was scanned for emissions conducted in the power cable from the LIFEPAK® 8.
- 2.10.3.4 The conducted susceptibility spike test was performed according to MIL-STD-462, Notice 3, Method CS06 on a chemical resistant counter top. Power was supplied via a customized metal connection box. The connection box has two power receptacles and four banana jacks on its front panel. Connections to the individual power lines are made in series through the banana jacks. Transient spikes of 100 volts, 10 microseconds were generated with a Solar Electronics model 8282-1 transient pulse generator\* and induced onto the power leads at the connection box banana jacks. The spikes were monitored with a Tektronix 2235 oscilloscope\* connected to a power receptacle on the connection box. The LIFEPAK\* 8 was plugged into the other receptacle on the connection box and placed in operation. It was visually observed for correct operation of visual displays while it was subjected to the power line spikes.
- 2.10.3.5 The conducted susceptibility test was performed according to MIL-STD-462, Notice 3, Method CSO2. The LIFEPAK® 8 was

placed on a grounded, copper-covered workbench. Radio frequency interference was induced on the power leads and measured at the LIFEPAK® 8 power cable. The frequency of the interference was incremented over the 50 kHz to 400 MHz range while the LIFEPAK® 8 was operated. It was visually observed for correct displays while it was subjected to the radio interference on the power leads. Each frequency was held for 15 seconds.

#### 2.10.4 Test findings

2.10.4.1 During the radiated emissions test, narrowband and broadband emissions which exceeded specification limits of MIL-STD-461A, Notice 4, were detected in the frequency ranges below.

Frequency	Emission exceeding standard
24 kHz - 474.2 MHz	0.3 - 66.7 dB (NB)
425 - 1000 MHz	13.6 - 31.7 dB (NB)

Criterion partially met.

2.10.4.2 The LIFEPAK® 8 was found susceptible to radiated emissions in the frequency ranges listed below. Evidence of susceptibility included service alert indications and erratic monitor displays and recordings.

Frequency	Maximum field strength without susceptibility
20 - 20.8 MHz	1.49 - 1.99 V/m
30 - 40.2 MHz	0.83 - 3.76  V/m

Criterion partially met.

- 2.10.4.3 Narrowband signals were detected in the frequency range 34 to 50 kHz, with magnitudes of 0.1 to 7.7 dB over specification limits, and in the frequency range 50 kHz to 50 MHz with magnitudes 1.6 to 38.7 dB over specification limits. Broadband emissions were detected in the frequency range 1 to 15 MHz, with magnitudes 0.5 to 30.6 dB over specification limits. Criterion partially met.
- 2.10.4.4 The susceptibility of the LIFEPAK® 8 to conducted radio frequency interference could not be determined. Noise generated on the power lines by the LIFEPAK® 8 was greater than the test signal level. The LIFEPAK® 8 was not affected by the presence of the test spikes on its power lines. Criterion partially met.
- 2.11 IN-FLIGHT HUMAN FACTORS EVALUATION

#### 2.11.1 Objective

To assess the physical and/or functional compatibility of the LIFEPAK® 8 while in use on board the aircraft.

#### 2.11.2 Criterion

The flight surgeon shall be able to operate the LIFEPAK® 8 without physical or functional restrictions aboard the aircraft. Major areas of concern include: Proper operation, visual displays, controls, maintainability, conductors, fasteners, test points, test equipment, fuses and circuit breakers, labels and coding, and safety.

#### 2.11.3 Test procedure

- 2.11.3.1 A human factors evaluation was performed IAW MIL-STD-1472D, AAMI Human Factors Engineering Guidelines, and UL-544 to ensure the compatibility of the LIFEPAK® 8 and the in-flight environment. The flight surgeon conducted the test wearing a flight suit, flight gloves, and an SPH-4 flight helmet. An evaluation of the compatibility with the nuclear, biological, and chemical (NBC) protective equipment was not conducted. Due to restrictions of the AWR, testing was conducted during daylight hours only.
- 2.11.3.2 The LIFEPAK® 8 was placed on the top pan of the litter carousel which was configured for four patients. The litter carousel was flown in the "load" position (lateral to the long axis of the helicopter). The LIFEPAK® 8 was tested in both the defibrillation and monitoring modes in the flight scenarios noted in sections 3.1 and 3.2).

#### 2.11.4 Test findings

During the in-flight human factors evaluation, the LIFEPAK® 8 was found to be satisfactory in all but two categories of the evaluation criteria. First, the deficiencies noted in the laboratory evaluation (paragraph 1.5.1.3) were exacerbated by the cramped quarters in the aircraft, and second, the inability of the flight surgeon to hear the audio alarms while wearing the required flight ensemble in the noisy environment produced by the aircraft. However, all audio alarms on the LIFEPAK® 8 are backed up by visual alarms which are acceptable. Criterion partially met.

#### 2.12 IN-FLIGHT EMI/EMC CHARACTERISTICS TEST

#### 2.12.1 Objective

To assess the EMI/EMC characteristics of the LIFEPAK $^{ullet}$  8 with the host aircraft and its installed systems.

#### 2.12.2 Criteria

2.12.2.1 The LIFEPAK\* 8 shall not radiate EMI to disrupt or interfere with other equipment or systems aboard the aircraft.

2.12.2.2 The aircraft shall not radiate EMI to disrupt or interfere with the LIFEPAK $^{\oplus}$  8's operation.

#### 2.12.3 Test procedure

A qualitative EMI/EMC assessment was performed with both the LIFEPAK® 8 and the aircraft operating as source and victim. The LIFEPAK® 8 and applicable aircraft instruments and systems were monitored for unusual operation, readings, surges, or power anomalies for each checklist item (see 3.2.3 Inflight test data card).

#### 2.12.4 Test findings

- 2.12.4.1 There were no adverse instances of EMI/EMC noted with the LIFEPAK $^{ullet}$  8 acting as either the source or victim. Criterion met.
- 2.12.4.2 There were no adverse instances of EMI/EMC noted with the aircraft acting as either the source or victim. Criterion met.

#### Section 3. Supporting documentation

#### 3.1 DETAILED TEST INFORMATION

#### 3.1.1 General information

- 3.1.1.1 LIFEPAK® 8 testing is not considered a major action significantly affecting the quality of the human environment and therefore qualifies for categorical exclusion A-28, AR 200-1, Appendix A.
- 3.1.1.2 A safety pilot will be designated for each flight. Flight operations will be conducted IAW the aircraft operator's manual, appropriate aircrew training manuals, and test item technical data.

#### 3.1.2 Material description

3.1.2.1 The Physio Control LIFEPAK $^{\bullet}$  8 defibrillator/monitor is a modular system in which the units may be used together or separately.

The ECG monitor has an internal battery and a line voltage input for independent operation. It has a 3 x 4-inch CRT cardio-scope which displays real time ECG and digital indications of heart rate, alarm settings, and trace size. Pushbutton switches on the front panel of the ECG monitor may be used to turn power on and off, set alarm limits, turn alarms on and off, set QRS beep volume, freeze the ECG trace, select leads, insert a calibration pulse, and control trace speed. A paper strip chart recorder also is a part of the monitor module which provides delayed or real time ECG recording and event marking. It may also be set for automatic activation when alarm limits are violated. Patient connection is made through a 6-pin Physio Control patient cable connector.

The defibrillator has an internal battery and a line voltage input for independent operation. The paddles are stored upright in slots on the front panel. The paddle cables retract into a compartment below the paddles. Energy levels of 10, 20, 30, 50, 100, 200, 300, and 360 joules are selected by a rotary switch. "Low" energy levels are selected in unit increments from 1 to 10 joules by pushbutton. Other pushbuttons turn power on and off, initiate the charge cycle, and select the synchronized discharge mode. A digital readout displays available energy when the defibrillator is energized. A cassette receptacle is located on the top of the defibrillator module which allows the use of auxiliary paddles or external pacing.

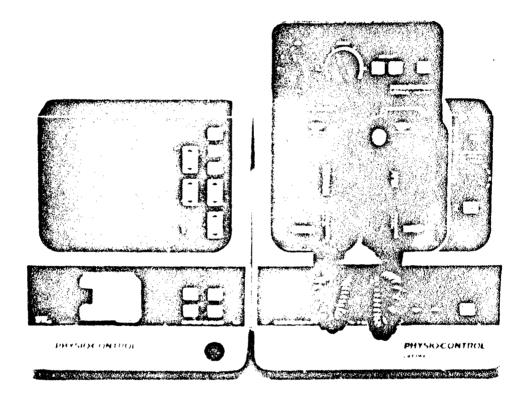
When the defibrillator and the monitor are used together, they are attached with fin connectors located on the side of each

- unit. A connector bar supplies line voltage to both units at the same time. When the synchronized defibrillation mode is selected, the defibrillator receives the QRS from the monitor module and a "SYNC MODE" message appears on the CRT screen.
- 3.1.2.2 Method of operation: The defibrillator and monitor modules connect together either by a latching fin assembly or by an accessory cable. Both methods provide three communication channels through optical ports. With both modules connected together, the defibrillator power button will energize both units and the ECG leads selector will be set for "paddles." When only the monitor is energized, the lead selector will be set for lead The lead selector mode is displayed on the CRT screen below the heart rate readout. System integrity is continuously monitored by six integral microprocessors which check read only memory (ROM), random access memory (RAM), and software module check sums. Any faults will result in a "SERVICE" alert message. The monitor is controlled by two panels of pushbuttons that provide logic signals to an executive microprocessor. The upper panel pushbuttons control ECG acquisition, alarms and display functions; lower panel pushbuttons operate the annotating record-The defibrillator is controlled by two microprocessors. Lower panel pushbuttons control synchronized mode settings and low-level power selections. Upper panel pushbuttons control power on/off, energy selection, and charge initiation. Charge initiation also may be controlled with a button on the apex paddle. Energy discharge is controlled solely by paddle discharge switches.
- 3.1.2.3 Dimensions: <u>ECG module</u>:  $10.5 \times 9.5 \times 11.25$  in  $(26.7 \times 24.1 \times 28.6 \text{ cm})$ . <u>Defibrillator module</u>:  $9.75 \times 10.25 \times 11$  in  $(24.8 \times 26 \times 27.9 \text{ cm})$ .
- 3.1.2.4 Weight: ECG module: 16.6 lbs (7.55 kg). Defibrillator module: 19.6 lbs (8.91 Kg)
- 3.1.2.5 Power requirements: <u>ECG module</u>: 120 VAC nominal, 45 watts maximum. Battery type is nickel-cadmium, with a typical capacity of 2.5 hours continuous monitoring or 1 hour continuous recording (or any linear combination). Charge time is 20 hours for a depleted battery. <u>Defibrillator module</u>: 120 VAC nominal, 160 watts maximum. Battery type is nickel-cadmium, with typical capacity of 25 360-joule discharges. Charge time is 20 hours for a depleted battery. Power cords are 8 ft long, type SJTW-A, 3C/16AWG conductor, E58188 VW-1.
- 3.1.2.6 Environmental considerations: Atmospheric pressure, 797 to 500 mmHg (-570 to +11000 ft); relative humidity, 0 to 95 percent (noncondensing) at 0 to 34°C, 0 to 80 percent (noncondensing) at 34 to 45°C; operating temperature 0 to 45°C; storage temperature, -30 to +65°C.

- 3.1.2.7 ECG common mode rejection: 100 dB minimum with respect to chassis ground with 51K ohms imbalance at 60 Hz; 65 dB with respect to isolated ground.
- 3.1.2.8 Cardioscope display: Size, 3 in  $\times$  4 in, nonfade; sweep speed, 25  $\pm$  1 mm/sec, or 50  $\pm$  2 mm/sec; frequency response, 1 to 30 Hz.
- 3.1.2.9 Recorder display: Paper size, 50 mm  $\times$  30 m (100 ft); paper speed, 25  $\pm$  1 mm/sec, or 50  $\pm$  2 mm/sec; recorder modes, real time or 5 sec delay; frequency response, 0.05 to 100 Hz (diag), 1 to 30 Hz (delay), annotation is available.
- 3.1.2.16 Defibrillator charge time: Charge to 360 joules in less than 10 sec at 25°C with AC power or fully charged battery; charge to 360 joules in less than 12 sec with battery operation after 15 maximum discharges.
- 3.1.2.11 Defibrillator output paddles: Electrode area, 82 cm<sup>2</sup>; cord length, 3 m (10 ft); discharge control, pushbuttons on both paddles in series.
- 3.1.2.12 Defibrillator synchronizer: Defibrillator will discharge 20 ms after marker on cardioscope (R-wave).

# 3.2 TEST DATA

# 3.2.1 Phot graphic description



# 3.2.2 Aircraft equipment list

Item No.	Nomenclature
1	Receiver radio R-1496A/ARN-89
_	(automatic direction finder)
2	Displacement gyro CN-1314/A
3	Gyro directional CN-998/ASN-43
4	Signal data converter CV-3338/ASN-128
5	Receiver R-2139/ARN-123
•	(VOR/LOC/MB/GS)
6	Command instrument system processor 70600- 01038-101
7	SAS amplifier 70901-02908-104
	(flight control stability augmentation system)
8	Rate gyro TRU-2A/A
9	Amplifier, impedance AM-4859A/ARN-89
10	Cargo hook FE-7590-145
11	Receiver, radar RT-1193/ASN-128
	(doppler navigation receiver)
12	Barometric altimeter AAU-31/A-1
13	Barometric altimeter AAU-32A
14	Receiver/transmitter RT-1300/ARC-186
	(VHF-AM and/or FM radio)
15	UHF-AM radio set RT-1518/ARC-164
16	Interphone control C6533/ARC
	(aircraft intercom control)
17	Receiver/transmitter RT-1115D/APN-209
	(radar altimeter)
18	Indicator altimeter ID-1917C/APN-209
	(radar altimeter)
19	Control radio set C-7392A/ARN-89
	(automatic direction finder)
20	Comparator signal data CM-482/ARC-186
21	(comparator for ARC-186)
21	Receiver/transmitter RT-1296A/APX-100
22	(transponder with IFF)
22	Computer display unit CP-1252/ASN-128
23	(doppler navigation system)
	Compass set controller C-8021E/ASN75
24	Magnetic compass - standby MS-17983-4

# 3.2.3 <u>In-flight test data card</u>

#### DATA CARD FORMAT

# GUIDELINE FOR DATA COLLECTION

# IN-FLIGHT SUITABILITY TEST OF MEDICAL ITEMS

1.	Installation/removal.	Suitable Yes No	Comments
	<ul><li>a. Weight and balance</li><li>(DD Form 365-4, Clearance</li><li>Form F).</li></ul>	x	
	b. Space/area allocation.		
	<pre>(1) Operational requirements.</pre>	x	
	(2) Storage requirements.	x	
	c. Interface connections (safe, positive, secure).	x	•
	<pre>d. Installation/removal (expedient/easily achieved).</pre>	x	
	<pre>e. Mounting/final config- uration (functional/stable).</pre>	X	
2.	Operations and performance.	Suitable Yes No	Comments
	a. Manufacturer's operating instruction.	x	
	<ul><li>b. Medical item operation before aircraft run-up.</li></ul>	x	
	c. System interface during aircraft engine run-up and medical item operation (EMI switchology checklist).	x	
	(1) Aircraft voltage output.	x	

	Suitable Yes No	Comments
(2) Flight control function (UH-60).	x	
(3) Stabilator function (UH-60).	X	
(4) Radio communication vs medical item operation.		
(a) FM	x	
(b) UHF	x	
(c) VHF	x	
(5) Navigation equipment vs medical item operation.		
(a) Transponder	<b>x</b> .	
(b) ADF	X	
(c) VOR	X	
(d) DOPPLER	x	
(6) Radar altimeter operation vs medical item operation.	x	
d. System interface during air- craft hover and medical item operation (EMI switchology check- list).		
(1) Voltage output.	n/a	
(2) Radio communication vs medical item operation.		
(a) FM	x	
(b) UHF	x	
(c) VHF	x	

(3) Navigation equipment operation vs medical item operation.	Suitable Yes No	Comments
(a) Transponder	x	
(b) ADF	x	
(c) VOR	X	
(d) DOPPLER	X	
e. Flight mission profile vs medical item operation (EMI switchology checklist).		
<pre>(1) Straight and level (1000 ft MSL for 20 minutes).</pre>		
<pre>(a) Compatibility of flight mode and medical item operation.</pre>	x	
<pre>(b) Radio communication vs medical item opera- tion.</pre>		
<u>a</u> . FM	x	
b. UHF	x	
c. VHF	X	
(2) NOE (20 minutes). compatibility of flight mode and medical item operation.	X	
(3) FM homing (10 minutes).	X	
(4) DOPPLER navigation vs medical item operation.		
<pre>(a) Initialize function.</pre>	x	
(b) Fix function.	X	
(c) Update function.	x	

	Suitable Yes No	Comments
<pre>(5) VOR navigation vs medical item operation.</pre>	x	
<pre>(6) ILS approach vs medical item operation.</pre>	х	
f. Medical item operation after engine shutdown (external power source).	x	
g. Restrictions to the medical item's use (i.e., electrical connectors).	x	
h. Deviations from the labor- atory test results.		
<pre>(1) Electrical/ electronic.</pre>	None	
<pre>(2) Mechanical environment.</pre>	None	
<pre>(3) Human factors (user interface, controls, markings, lighting, egress).</pre>	None	
(4) Safety.	None	

3. Deviations from the in-flight test protocol.

The VOR navigation portion of the in-flight test conducted at 2000 feet MSL due to air traffic control clearance.

# 3.2.4 EMI switchology checklist

# EMI SWITCHOLOGY CHECKLIST UH-60 AIRCRAFT IN-FLIGHT SUITABILITY OF MEDICAL ITEMS

ENG INSTRUMENTS/CDU	No EMI Affect	EMI Affected Gnd Flt	Explanation
Fuel quantity Fuel indicator test XMSN oil temperature XMSN oil pressure #1 engine oil temperature #2 engine oil temperature #1 engine oil pressure #2 engine oil pressure #2 TGT #1 TGT #2 TGT #1 Ng speed #2 Ng speed CDU digits on/off CDU instruments dim	x x x x x x x x x x x		
ENG INSTRUMENTS/PLT PDU	No EMI Affect	EMI Affected Gnd Flt	Explanation
<pre>#1 engine RPM #2 engine RPM Rotor RPM #1 torque #2 torque</pre>	x x x x x		
ENG INSTRUMENTS/COPLT PDU	No EMI Affect	EMI Affected Gnd Flt	Explanation
<pre>#1 engine RPM #2 engine RPM Rotor RPM #1 torque #2 torque</pre>	X X X X	·	

ENG CONTROLS	No EMI EMI Affected Affect Gnd Flt	Explanation
<pre>#1 overspeed #2 overspeed RPM switch #1 engine anti-ice #2 engine anti-ice #1 inlet anti-ice #2 inlet anti-ice</pre>	x x x x x x	
RADIO EQUIPMENT	No EMI EMI Affected Affect Gnd Flt	Explanation
ICS, C-6533 ARC VHF-FM, ARC-186/115 VHF-AM, ARC-186/115 UHF-AM, ARC-164(V) Crypto, KY-28 Radio retransmissions PLN Transponder, APX-100(V) KIT-1A/TSEC IFF computer	X X X X Not installed Not installed X Not keyed with code	
MISSION EQUIPMENT	No EMI EMI Affected Affect Gnd Flt	Explanation
RWR, APR-39(V) IR CM, ALQ-144 Chaff dispenser, M-130 Cargo hook system	Not installed Not installed Not installed X	
HYDRAULIC CONTROL SYSTEM	No EMI EMI Affected Affect Gnd Flt	Explanation
Backup hydraulic pump Servo off 1st stage/PLT Servo off 2nd stage/PLT Servo off 1st stage/COPLT Servo off 2nd stage/COPLT Hydraulic leak test Tail servo Boost servos	X X X X X X	

FUEL SYSTEM	No EMI Affect	EMI Affected Gnd Flt	Explanation
Fuel pump switch Fuel boost pump #1 Fuel boost pump #2 Fuel cont panel ESSS	X X X Not insta	lled	
WARNING SYSTEM	No EMI Affect	EMI Affected Gnd Flt	Explanation
Low rotor RPM Master caution Caution advisory Fire warning AFCS Stabilator #1 engine out #2 engine out	x x x x x x x		
NAVIGATION INSTRUMENTS	No EMI Affect	EMI Affected Gnd Flt	Explanation
ADF Magnetic compass CONUS NAV, ARN-123 DOPPLER, ASN-128 Gyro mag compass (PLT) Gyro mag compass (COPLT) Compass cont panel, ASN-75 HSI	x x x x x x x		
FLIGHT INSTRUMENTS	No EMI Affect	EMI Affected Gnd Flt	Explanation
Radar altimeter Stabilator pos indicator VSI CIS mode select SAS 1 SAS 2 FPS Trim Go-around enable Cyclic trim release Cyclic stick trim ALR encoder	x x x x x x x x x x x		

FLIGHT INSTRUMENTS (CONT)	No EMI Affect	EMI Affected Gnd Flt	Explanation
HSI/VSI mode select (PLT)  DPLR  VOR/ILS  BACK CRS  FM HOME  TURN RATE  CRS HDG  VERT GYRO  BRG 2  HSI/VSI Mode Select (COPLT)  DPLR  VOR/ILS  BACK CRS  FM HOME  TURN RATE  CRS HDG  VERT GYRO  BRG 2	x x x x x x x x x x x		
MISCELLANEOUS EQUITMENT	No EMI Affect	EMI Affected Gnd Flt	Explanation
Blade deice	Not tested	1	Ambient tempera- ture was out of test lim- its.
Windshield anti-ice Pitot heat Vent blower Windshield wiper Heater APU Generator #1 Generator #2 Generator APU Air source heat start Tail wheel lock Gyro erect	x x x x x x x x x x		165.

LIGHTING	No EMI Affect	EMI Affected Gnd Flt	Explanation
Cockpit utility	x		
Cockpit flood	X		
Cabin dome	X		
Search light	X		
Search light control	X		
Landing light	X		
Flt instr lights (PLT)	X		
Flt instr lights (COPLT)	X		
Nonflight instr lights	X		
Console lights, upper	X		
Console lights, lower	X		
Position lights	X		
Formation lights	X		
Anticollision lights	X		
NVG lighting	X		

# 3.2.5 Battery life evaluation

# Battery Life Evaluation Report Form

Nomenclature: Defibrillator/monitor

Manufacturer: Physio Control

Model number: LIFEPAK® 8

Serial number: 00007417 (defibrillator), 00007513 (monitor)

Military item number: None

Options installed: None

Manufacturer battery life specification: 2.5 hours monitor operation, or 1 hour continuous recording with a heart rate of 60 and 1.5 cm cardioscope display, or 25 energize-fire defibrillator cycles.

Specified battery recharge time: 20 hours to fully charge depleted battery.

Specified mode of operation under battery power: Monitor operated an average of 2.5 hours while 21 energize-fire cycles were completed with the defibrillator before a low battery indication.

Overall performance: Pass

Measurements: The unit averaged 2.5 hours of monitor operation.

Comments: The unit was operated continuously in the monitor mode and then operated with monitoring for 1 hour followed by 10 consecutive 360 joule defibrillator energize-fire cycles. The procedure was repeated three times for each mode of operation.

# 3.2.6 Electrical safety test

# Electrical Safety Test Report Form

Nomenclature: Defibrillator/monitor

Manufacturer: Physio Control Model number: LIFEPAK® 8

Serial number: 00007417 (defibrillator), 00007513 (monitor)

Military item number: None

Options installed: External pacer cassette

Date of test: 1 Nov 88

#### Measurements:

Grounding conductor resistance (milliohms): 57.7

Leakage current - Case to ground (microamperes):

unit off, grounded, normal polarity unit off, ungrounded, normal polarity unit off, ungrounded, reverse polarity	4.0 37.7 41.0
unit on, grounded, normal polarity unit on, ungrounded, normal polarity unit on, ungrounded, reverse polarity	4.6 50.2 53.0

#### MAXIMUM LIMITS:

<pre>ground r&gt;sistance (milliohms):</pre>	150
current (grounded, type A unit):	10
current (ungrounded, type A unit):	100
current (grounded, type B unit):	50
current (ungrounded, type B unit):	500

Comments on item setup or checks: None

Comments on test run (including interruptions): None

Comments on other data: None

# 3.2.7 Human factors evaluation

# Human Factors Evaluation Report Form

Nomenclature: Defibrillator/monitor

Manufacturer: Physio Control

Model number: LIFEPAK® 8

Serial number: 00007417 (defibrillator), 00007513 (monitor)

Military item number: None

Options installed: External pacer cassette

Date of test: 1 Nov 88

Item configuration during test: Item prepared for operation,

sitting on a countertop.

#### Checklist for HFE

RESULTS

#### VISUAL DISPLAYS:

Satisfactory

display type, format, content location of displays indicator lights scalar displays color coding legends and labels cathode ray tubes counters flags, go/no go, center-null indicators

Comments: No control to vary display intensity provided.

# CONTROLS:

Unsatisfactory

location characteristics of controls labeling control - display relationships

Comments: Paddle handles located in "wells," difficult to grasp, especially with gloves. A pacing cassette is an obstacle when carrying defibrillator unit by its handle.

TIME REQUIRED TO PREPARE FOR OPERATION (list in comment,

Comments: Less than 5 minutes.

### MAINTAINABILITY:

Unsatisfactory

component location
component characteristics
rests and stands
covers, cases, access doors
handles
lubrication
component mounting
cord storage provisions
external accessibility
internal accessibility
list special tools required
list realistic inspection requirements
list realistic inspection intervals

Comments: Unit may be too heavy to be considered portable.

### CONDUCTORS:

Satisfactory

binding and securing length protection routing conductor coding fabrication connectors

Comments: None

### **FASTENERS:**

Satisfactory

access through inspection panel covers enclosure fasteners device mounting bolts and fasteners

Comments: None

TEST POINTS:

N/A

general
location and mounting
test point labeling and coding

Comments: None

TEST EQUIPMENT:

Satisfactory

general
equipment self-test
indicators (list in comments)
controls
positive indication of proper operation

Comments: None

FUSES AND CIRCUIT BREAKERS:

Satisfactory

external accessibility
easy replacement or reset by operator

Comments: Fuses accessible from rear panel.

LABELS AND CODING:

Satisfactory

placed above controls and displays near or on the items they identify not obscured by other equipment components describe the function of the items they identify readable from normal operating distance conspicuous placards adjacent to hazardous items

Comments: Excellent operator and service manuals

SAFETY:

Satisfactory

manual
materials
fire and explosive protection
operator protection from mechanical hazards
patient protection from mechanical hazards
electrical safety (operator and patient)

Comments: None

# 3.2.8 Altitude test

# Altitude Test Report Form

Nomenclature: Defibrillator/monitor

Manufacturer: Physio Control

Model number: LIFEPAK® 8
Serial number: 00007417 (defibrillator), 00007513 (monitor)

Military item number: None

Options installed: None

Date of test: 25 Oct 88

Item ( nfiguration during test: Item turned on in the standby mode, operating on DC (battery) power, sitting on chamber floor.

Performance test criteria: Consistent and accurate displays and

measurements

Ambient conditions outside chamber:

Temperature Humidity 57% RH Barometric pressure 1 atm

PRETEST DATA

Pretest performance check:

Item functional (based on performance test criteria): Yes

Installation of item in test facility:

list connections to power None (battery)

list connections to simulators None list connections to dummy loads None

list unconnected terminals Serial port

IN-TEST DATA

Time of test start: 0908

POSTTEST DATA

Posttest performance check (complete check of item and accessories):

Time of test end: 1035

Item functional (based on performance test criteria): Yes

Deviation from pretest : None

Comments on item setup or checks: None

Comments on test run (including interruptions): Tested with
 test and evaluation item 6.

Comments on other data: None

#### 3.2.9 Vibration test

# Vibration Test Report Form

Nomenclature: Defibrillator/monitor

Manufacturer: Physio Control Model number: LIFEPAK® 8

Serial number: 00007417 (defibrillator), 00007513 (monitor)

Military item number: None

Options installed: None

Date of test: 25 Oct 88

Item configuration during test: Item strapped down on vibration

table fixture; AC and DC operation.

Performance test criteria: Consistent and accurate measurements

and displays.

PRETEST DATA

Pretest performance check:

Item functional (based on performance test criteria): Yes

Installation of item in test facility:

list connections to power 120 VAC

list connections to simulators PEI analyzer list connections to dummy loads PEI analyzer

list unconnected terminals None

Ambient conditions

Temperature 73°F
Humidity 55% RH
Barometric pressure 1 atm

IN-TEST DATA

Data and performance checks during test:

Times of test start:

Time at first check:

X: 1020 Y: 1300 Z: 1440

Item functional (based on performance test criteria): Yes

Deviation from pretest: None

Time at second check:

X: 1120

Y: 1400

Z: 1545

Item functional (based on performance test criteria): Yes

Deviation from pretest: None

POSTTEST DATA

Posttest performance check (complete check of item and accessories):

Item functional (based on performance test criteria): Yes

Item intact: Yes

Deviation from pretest: None

Comments on item setup or checks:
Times are on different days

Comments on test run (including interruptions): None

Comments on other data: None

# 3.2.10 High temperature test

High Temperature Test (Equipment Operating) Report Form

Nomenclature: Defibrillator/monitor

Manufacturer: Physio Control Model number: LIFEPAK® 8

Serial number: 00007417 (defibrillator), 00007513 (monitor)

Military item number: None

Options installed: External Pacer Cassette

Date of test: 25 Nov 88

Item configuration during test: Unit was sitting on chamber

floor, ready for operation.

Performance test criteria: Consistent and accurate displays and measurements.

Ambient conditions outside chamber:

Temperature 23°C
Humidity 63% RH
Barometric Pressure 1 atm

PRETEST DATA

Pretest performance check:

Item functional (based on performance test criteria): Yes

Installation of item in test facility:

list connections to power
list connections to simulators
list connections to dummy loads
list connections to power
light VAC
list simulator (ECG)
Neurodyne Dempsey defibrillator analyzer

list unconnected terminals

distance from north wall (meters)

distance from south wall (meters)

distance form east wall (meters)

distance from west wall (meters)

distance from ceiling (meters)

distance from floor (meters)

0.0

IN-TEST DATA

Time of test start: 0815

# Performance checks during test:

# First check:

Time: 0855
Temperature: 49°C
Humidity: 16% RH
Barometric pressure: 1 atm

Item functional (based on performance test criteria)

Yes, all OK

Deviation from pretest: None

## Second check:

Time: 0930
Temperature: 49°C
Humidity: 16% RH
Barometric pressure: 1 atm

Item functional (based on performance test criteria)

Yes, all OK

Deviation from pretest: None

### Third check:

Time: 1000
Temperature: 49°C
Humidity: 15% RH
Barometric pressure: 1 atm

Item functional (based on performance test criteria)

Yes, all OK

Deviation from pretest: None

# POSTTEST DATA

#### Posttest performance check:

(complete check of item and accessories)

Time of test end: 1100

Item functional (based on performance test criteria)

Yes, all OK

Deviation from pretest: None

### Comments on itsm set-up or checks:

Tested at same time with test and evaluation program item 6.

Comments on test run (including interruptions): None

Comments on other data: None

### 3.2.11 High temperature storage test

High Temperature Test (Equipment in Storage) Report Form

Nomenclature: Defibrillator/monitor

Manufacturer: Physio Control Model number: LIFEPAK® 8

Serial number: 00007417 (defibrillator), 00007513 (monitor)

Military item number: None

Options installed: None

Date of test: 29 Nov 88

Item configuration during test: Sitting on chamber floor, in

storage, not operating.

Performance test criteria: Consistent and accurate displays and

measurements.

Ambient conditions outside chamber:

Temperature 20°C Humidity 43% RH Barometric pressure 1 atm

PRETEST DATA

Pretest performance check:

Item functional (based on performance test criteria): Yes

Installation of item in test facility:

list connections to power None list connections to simulators None list connections to dummy loads None list unconnected terminals All distance from north wall (meters) 0.75 distance from south wall (meters) 0.75 distance form east wall (meters) 2.0 distance from west wall (meters) 2.0 distance from ceiling (meters) 2.6 distance from floor (meters) 0.0

Time of test start: 0820

# POSTTEST DATA

Posttest performance check:
 (complete check of item and accessories)

Time of test end: 1445

Item functional (based on performance test criteria): Yes

Deviation from pretest: None

Comments on item setup or checks: None

Comments on test run (including interruptions): None

Comments on other data:

tested at same time with test and evaluation program
item 6.

# 3.2.12 Low temperature test

Low Temperature Test (Equipment Operating) Report Form

Nomenclature: Defibrillator/monitor

Manufacturer: Physio Control Model number: LIFEPAK® 8

Serial number: 00007417 (defibrillator), 00007513 (monitor)

Military item number: None

Options installed: None

Date of test: 25 Nov 88

Item configuration during test: Sitting on chamber floor, ready

for operation.

Performance test criteria: Consistent and accurate displays and

measurements.

Ambient conditions outside chamber:

Temperature 23°C Humidity 20% RH Barometric pressure 1 atm

PRETEST DATA

Pretest performance check:

Item functional (based on performance test criteria): Yes

Installation of item in test facility:

list connections to power 120 VAC list connections to simulators Dynatech Nevada Defi-

list connections to dummy loads brillator Analyzer

Dynatech Nevada Defi-

brillator Analyzer

list unconnected terminals

distance from north wall (meters)

distance from south wall (meters)

distance form east wall (meters)

distance from west wall (meters)

distance from ceiling (meters)

2.0

distance from floor (meters) 0.0

Time of test start: 1200

# Performance checks during test:

#### First check:

Time: 1230
Temperature: 0°C
Humidity: n/a
Barometric pressure: 1 atm

Item functional (based on performance test criteria): Yes

Deviation from pretest: None

### Second check:

Time: 1300
Temperature: 0°C
Humidity: n/a
Barometric pressure: 1 atm

Item functional (based on performance test criteria): Yes

Deviation from pretest: None

# Third check:

Time: 1330
Temperature: 0°C
Humidity: n/a
Barometric pressure: 1 atm

Item functional (based on performance test criteria): Yes

Deviation from pretest: None

# POSTTEST DATA

#### Posttest performance check:

(complete check of item and accessories)

Time of test end: 1405

Item functional (based on performance test criteria): Yes

Deviation from pretest: None

#### Comments on item set-up or checks:

Tested at same time with test and evaluation program item 6.

# Comments on test run (including interruptions):

Condensation on defibrillator/monitor was allowed to dry before final performance check.

Comments on other data: None

# 3.2.13 Low temperature storage test

Low Temperature Test (Equipment in Storage)
Report Form

Nomenclature: Defibrillator/monitor

Manufacturer: Physio Control Model number: LIFEPAK® 8

Serial number: 00007417 (defibrillator), 00007513 (monitor)

Military item number: None

Options installed: None

Date of test: 1 Dec 88

Item configuration during test: Sitting on chamber floor, in

storage, not operating.

Performance test criteria: Consistent and accurate displays and

measurements

Ambient conditions outside chamber:

Temperature 20°C Humidity 49% RH Barometric pressure 1 atm

PRETEST DATA

Pretest performance check:

Item functional (based on performance test criteria): Yes

Installation of item in test facility:

list connections to power None list connections to simulators None list connections to dummy loads None list unconnected terminals All distance from north wall (meters) 0.75 distance from south wall (meters) 0.75 distance form east wall (meters' 2.0 distance from west wall (meters) 2.0 distance from ceiling (meters) 2.6 distance from floor (meters) 0.0

Time of test start: 0807

# POSTTEST DATA

Posttest performance check:
 (complete check of item and accessories)

Time of test end: 1434
Item functional (based on performance test criteria): Yes
Deviation from pretest: None

Comments on item setup or checks: None

Comments on test run (including interruptions): None

Comments on other data: The unit was allowed to return to ambient conditions overnight before final performance check.

# 3.2.14 Humidity test

# Humidity Test Report Form

Nomenclature: Defibrillator/monitor

Manufacturer: Physio Control

Model number: LIFEPAK® 8
Serial number: 00007417 (defibrillator), 00007513 (monitor)

Military item number: None

Options installed: External pacer cassette

Date of test: 5 Dec 88

Item configuration during test: The unit was sitting on the

chamber floor, ready for operation.

Performance test criteria: Consistent and accurate displays and

measurements.

Ambient conditions outside chamber:

Temperature 19°C Humidity 49% RH Barometric pressure 1 atm

PRETEST DATA

Pretest performance check:

Item functional (based on performance test criteria): Yes

Installation of item in test facility:

list connections to power	120 VAC
list connections to simulators	BioTek
list connections to dummy loads	Defibrillator analyzer
list unconnected terminals	None
distance from north wall (meters)	0.75
distance from south wall (meters)	0.75
distance form east wall (meters)	2.0
distance from west wall (meters)	2.0
distance from ceiling (meters)	2.6
distance from floor (meters)	0.0

IN-TEST DATA

Time of test start: 1110

# Performance checks during test:

#### First check:

Time: 1155
Temperature: 29.5°C
Humidity: 95% RH
Barometric pressure: 1 atm

Item functional (based on performance test criteria)

No, synchronized defibrillation

mode not operational

Deviation from pretest: None

#### Second check:

Time: 1240
Temperature: 29.5°C
Humidity: 95% RH
Barometric pressure: 1 atm

Item functional (based on performance test criteria)

No, synchronized defibrillation

mode not operational

Deviation from pretest: None

### Third check:

Time: 1325
Temperature: 29.5°C
Humidity: 95% RH
Barometric pressure: 1 atm

Item functional (based on performance test criteria)

No, synchronized defibrillation

mode not operational

Deviation from pretest: None

#### Fourth check:

Time: 1410
Temperature: 29.5°C
Humidity: 95% RH
Barometric pressure: 1 atm

Item functional (based on performance test criteria)

No, synchronized defibrillation

mode not operational

Deviation from pretest: None

# Fifth check:

Time: 1455
Temperature: 29.5°C
Humidity: 95% RH
Barometric pressure: 1 atm

Item functional (based on performance test criteria)

No, synchronized defibrillation

mode not operational

Deviation from pretest: None

POSTTEST DATA

Posttest performance check:

(complete check of item and accessories)

Time of test end: 1550

Item functional (based on performance test criteria): Yes

Deviation from pretest: None

Comments on item setup or checks: The "sync" mode was not operational during the test, but functioned properly when returned to ambient conditions. The recorder paper was moist during the test.

Comments on test run (including interruptions): None

Comments on other data:

This test item was tested with test and evaluation item 6.

# 3.2.15 Electromagnetic characteristics test

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

Electromagnetic Characteristics Testing
Evaluation of Performance

T & E Item Number: 07 Date: 1 Nov 88

Nomenclature: Defibrillator/monitor

Manufacturer: Physio Control Model number: LIFEPAK\* 8

Serial number: 00007417 (defibrillator), 00007513 (monitor)

Military item number: n/a

# Conducted Emissions Tests

CE01 Testing configuration(s): n/a
Performance (pass/fail): n/a

Comments: n/a

CE02 Testing configuration(s): Operating on copper work bench, ECG from defibrillator analyzer discharged into analyzer.

Performance (pass/fail): Fail

Comments: Emissions of 0.1 to 7.7 db over specification in range 34 to 50 MHz. Levels rise during defibrillator charge and at moment of discharge.

CE04 Testing configuration(s): Monitor only operating, then both monitor and defibrillator operating. Defibrillator charged and fired every 30 seconds.

Performance (pass/fail): Fail

Comments: NB emissions of 1.6 to 38.7 dB over specification across range of test; BB emissions 6.5 to 30.6 dB over specification, primarily in range 1 to 15 MHz.

# Conducted Susceptibility Tests

CS02 Testing configuration(s): Operating on test bench, connected to test jig.

Performance (pass/fail): n/a

Comments: Unable to test because noise generated by the unit is greater than the test signal (unable to measure test signal).

CS06 Testing configuration(s): Operating on counter top, connected to connection box.

Performance (pass/fail): Pass

Comments: Not susceptible to test spikes.

### Radiated Emissions Tests

RE02 Testing configuration(s): Operating on wooden test stand in the EMC chamber, AC and battery power, with monitor only and then with monitor and defibrillator together.

Performance (pass/fail): Fail

Comments: NB failures 0.3 to 66.7 dB over specification, 24 kHz to 474.2 mHz; BB emissions: 13.6 to 31.7 dB over specification, 425 to 1000 MHz.

### Radiated Susceptibility Tests

RS03

Testing configuration(s): Operating on the wooden test stand in the EMC chamber, AC power only. Performance (pass/fail): Fail Comments: Susceptible to 1.49 to 1.99 V/m from 20 to 20.8 MHz; 1.88 V/m at 30 MHz; and 0.83 to 3.76 V/m from 30 to 40.2 MHz. Erratic displays and service alerts noted as failure.

# 3.3 CRITERIA, SIGNIFICANT PROBLEMS, AND SUGGESTED IMPROVEMENTS

# 3.3.1 Criteria

Item			<u>Applicable</u>
No.	Criteria (Source)	Remarks	subparagraph
1	The physical inventory is conducted solely for investigation and documentation.	N/A	2.1.2.1
2	The LIFEPAK® 8 will display consistent and accurate measurements.	met	2.1.2.2
3	Verify manufacturer's specified full power internal battery life expectancy of 2.5 hours or 25 energize/fire cycles.	met	2.2.2
4	The LIFEPAK® 8 will meet the limits established in NAFP 99 for electrical safety of medical equipment.	met	2.3.2
5	The LIFEPAK* 8 will be rated satisfactory in all major categories of the evaluation. These include: Visual displays, controls, maintainability, conductors, fasteners, test points, test equipment, fuses and circuit breakers, labels and coding, and safety.	par- tially met	2.4.2
6	The LIFEPAK* 8 will display consistent and accurate measurements while exposed to an altitude equivalency of 15,000 feet above sea level.	met	2.5.2
7	The LIFEPAK* 8 will remain operational and display consistent and accurate measurements while exposed to vibrational stresses.	met	2.6.2
8	The LIFEPAK* 8 will display consistent and accurate measurements during the high temperature operation check.	met	2.7.2.1

9	The LIFEPAK® 8 will display consistent and accurate measurements after the high temperature storage.	met	2.7.2.2
10	The LIFEPAK® 8 will display consistent and accurate measurements during the low temperature operation check.	met	2.8.2.1
11	The LIFEPAK® 8 will display consistent and accurate measurements after the low temperature storage.	met	2.8.2.2
12	The LIFEPAK* 8 will display consistent and accurate measurements while exposed to a high humidity.	par- tially met	2.9.2
13	The LIFEPAK® 8 will not produce emissions in excess of the limits set forth in MIL-STD-461A, Notice 4, paragraph 6.13.	par- tially met	2.10.2.1
14	The LIFEPAK® 8 will not mal- function when it is subjected to radiated fields as specified in MIL-STD-461A, Notice 4, para- graph 6.20.	par- tially met	2.10.2.2
15	The LIFEPAK® 8 will not conduct emissions in excess of the limits set forth in paragraphs 6.1 and 6.2, MIL-STD-461A, Notice 4.	par- tially met	2.10.2.3
16	The LIFEPAK® 8 will not mal- function when it is subjected to conducted emissions as specified in paragraphs 6.7 and 6.10, MIL- STD-461A, Notice 4.	par- tially met	2.10.2.4
17	The flight surgeon will be able to operate the LIFEPAK® 8 with-out physical or functional restrictions aboard the aircraft.	par- tially met	2.11.2.1
18	The LIFEPAK* 8 will not radiate EMI to disrupt or interfere with the other equipment or systems aboard the aircraft.	met	2.12.2.2

- The aircraft will not radiate met 2.12.2.3 EMI to disrupt or interfere with the LIFEPAK\* 8.
- 3.3.2 Significant problems which require corrective action

None

3.3.3 Suggested improvements

None

#### 3.4 REFERENCES

- 3.4.1 Department of Defense. 1971. <u>EMI characteristics</u>, requirements for equipment. Washington, D.C. MIL-STD-461A, Notice 4. February.
- 3.4.2 Department of Defense. 1971. <u>EMI characteristics</u>, <u>measurement of</u>. Washington, D.C. MIL-STD-462, Notice 3. February.
- 3.4.3 Department of Defense. 1983. <u>Environmental test methods</u> and engineering quidelines. Washington, D.C. MIL-STD-810D. July.
- 3.4.4 Department of the Army. 1982. <u>Environmental protection</u> and <u>enhancement</u>. Washington, D.C. Army Regulation 200-1. June.
- 3.4.5 Department of the Army. 1987. Maintenance management procedures for medical equipment. Washington, D.C. TB 38-750-2. April.
- 3.4.6 Department of Defense. 1985. <u>Standard general requirements for electronic equipment</u>. Washington, D.C. MIL-STD-454K. February.
- 3.4.7 Underwriters Laboratory's, Inc. 1978. <u>Standard for safety. medical and dental equipment</u>. Chicago, Illinois. UL-544.
- 3.4.8 Department of Defense. 1989. <u>Human engineering design criteria for military systems</u>, equipment, and facilities. Washington, D.C. MIL-STF-1472D. March.
- 3.4.9 Association for the Advancement of Medical Instruments. Human factors engineering guidelines and preferred practices for the design of medical devices. Arlington, Virginia. AAMI-HE-1988. February.
- 3.4.10 Department of the Army. 1978. Operator's manual, UH-60 and EH-60 helicopter, with changes 1-5. Washington, D.C. TM 55-1520-237-10. January.
- 3.4.11 Department of the Army. 1987. <u>Maintenance management procedures for medical equipment</u>. Washington, D.C. TB 38-750-2. April.
- 3.4.12 National Fire Protection Association. 1987. <u>Standard for health care facilities</u>. Quincy, Massachusetts. NFPA 99. February.
- 3.4.13 Physio Control. 1987. Operating instructions, LIFEPAK® monitor/defibrillator. Redmond, Washington. P/N 803334-02.

3.4.14 Mitchell, G. W., and Adams, J. E. 1988. <u>Technical test and evaluation of aeromedical equipment</u>. Fort Rucker, AL: U.S. Army Aeromedical Research Laboratory. USAARL Letter Report LR-88-16-1-2.

#### 3.5 ABBREVIATIONS

AEST aeromedical equipment suitability test

atm atmosphere

AVSCOM U.S. Army Aviation Systems Command

AWR airworthiness release

BB broadband

BPM beats per minute

CAAF Cairns Army Airfield CRT cathode ray tube

dB decibel

DC direct current

ECG electrocardiograph

EMC electromagnetic compatibility EMI electromagnetic interference

fpm feet per minute

GFE government furnished equipment

GHz gigahertz Gpk gravity, peak

G(rms) gravity (root mean square)

Hz hertz

IAW in accordance with

ITOP in-flight test operating procedure

IGE in-ground effect

kHz kilohertz

KIAS knots indicated airspeed

LCD liquid crystal display LED light emitting diode

LIFEPAK\* 8 Physio Control defibrillator/monitor,

model LIFEPAK\* 8

MEDEVAC medical evacuation

MHz mega hertz

MIL-STD military standard

ml milliliter mm millimeter

mmHg millimeters of Mercury

MSL mean sea level

NAFP National Association of Fire Prevention

NB narrowband

NBC nuclear, biological and chemical

NiCad NVG nickel cadmium
night vision goggle

RAM RF random access memory radio frequency relative humidity read only memory

RH ROM

TB

technical bulletin

TFT

technical feasibility testing

T & E

test and evaluation

UES USAARL Universal Energy Systems, Inc. U.S. Army Aeromedical Research Laboratory

V/m

volts per meter

# 3.6 LIST OF MANUFACTURERS

3.6.1 Physio-Control Corporation 11811 Willows Road Northeast Post Office Box 97006 Redmond, WA 98073-9706

ţ,

- 3.6.2 Sikorsy Aircraft 6900 Main Street Stratford, CT 06601
- 3.6.3 Neurodyne-Dempsey, Inc. 200 Arrowhead Drive Carson City, NV 89701
- 3.6.4 Tenney Engineering, Inc. 1090 Springfield Road Post Office Box 3142 Union, NJ 07083
- 3.6.5 Unholtz-Dickey Corporation 6 Brookside Drive Wallingford, CT 06492
- 3.6.6 BioTek Instruments, Inc. 1 Mill Street Burlington, VT 05401
- 3.6.7 Solar Electronics Company 901 North Highland Avenue Hollywood, CA 90038
- 3.6.8 Tektronix, Inc P.O. Box 500 Beaverton, OR 97077

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